
Attachment XII

NORMALIZED CURRENT DISTRIBUTION – EBI Soft-Touch™ Electrodes Used with the Original SpinalPak® Stimulation System

EBI SpinalPak Soft-Touch Electrodes made by LecTec

CONSTRUCTION (see Figure I)

- Spunlace backing
- Stiff leadwire with molded connector
- Carbon Film
- Ag/AgCl eyelet soldered onto leadwire
- LecTec gel
- Mylar Liner

DIMENSIONS

- Diameter: 35 mm
- Shape: Round (circular)
- Surface Area: 9.62 cm²

ELECTRICAL TESTS

As seen from the electrical test data attached, the EBI Soft-Touch I electrode primarily delivers stimulation under the 10 mm eyelet (hotspot) rather than the full 35 mm electrode. The total impedance of the electrode was measured at 78 Ω .

CONCLUSION

A general purpose stimulation electrode as made by many manufacturers – Nothing unique and **not currently used with the SpinalPak II System.**

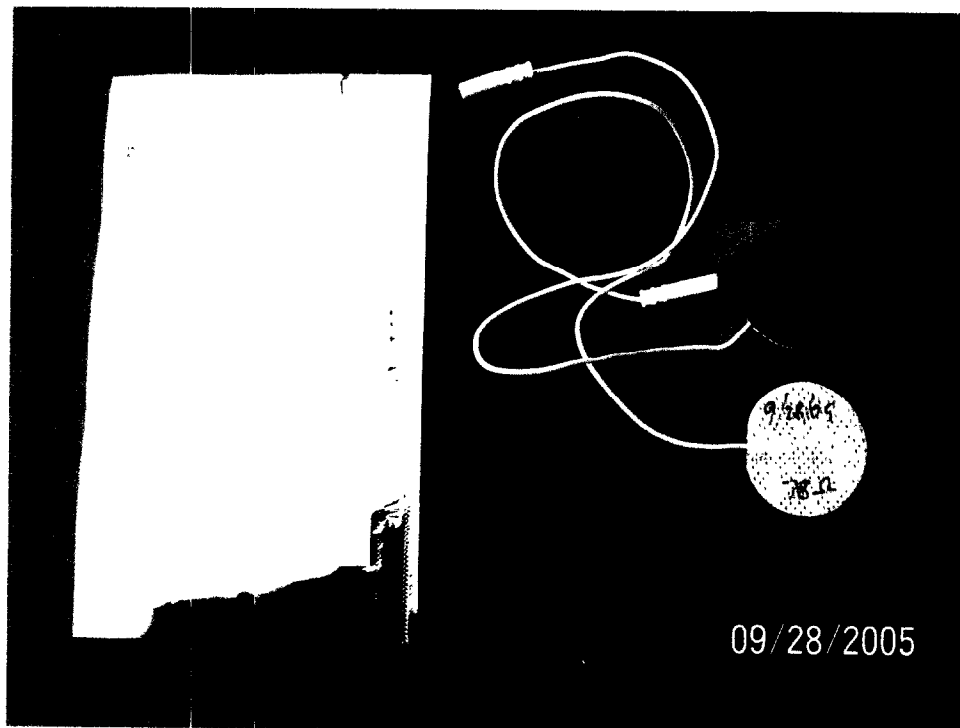


Figure I. Soft-Touch™ Electrodes made by LECTEC

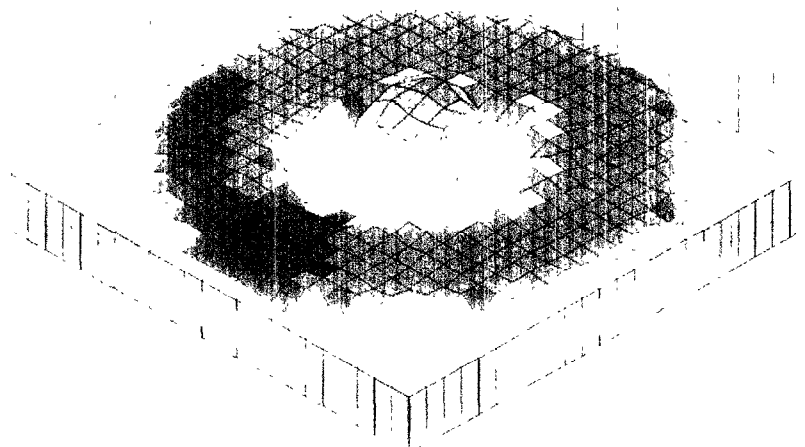


Figure 2. Current distribution map for LECTEC Soft-Touch Electrodes.

NORMALIZED CURRENT DISTRIBUTION – EBI Soft-Touch™ Electrodes used with the SpinalPak II® Stimulation System.

EBI SpinalPak Soft-Touch™ Electrodes made by Uni-Patch

CONSTRUCTION

- Spunlace backing
- Stiff leadwire with molded connector – 15 mm strip length
- Carbon Film with Ag/AgCl top coating (Standard Ag/AgCl coated PVC Carbon Film by Intelicoat – Product 4204)
- Ludlow RG-73P gel (Standard)
- Mylar Liner

DIMENSIONS

- Diameter: 35 mm
- Shape: Round (circular)
- Surface Area: 9.62 cm²

ELECTRICAL TESTS

As seen from the electrical test data attached (Figures 4 & 5), the EBI Soft-Touch II electrode has an even current distribution across the electrode; however, as demonstrated in the current distribution maps below, there is a streak of better conduction located at different places in the two samples tested. This is attributed to the inconsistency of the raw material used (Uni-Patch uses Intelicoat 4204 carbon film which is a cheaper, lower

quality of Intelicoat 4201). The total impedance of the two electrode samples were measured at 118 & 120 Ω , respectively.

CONCLUSION

A general purpose stimulation electrode as made by many manufacturers – Nothing unique.

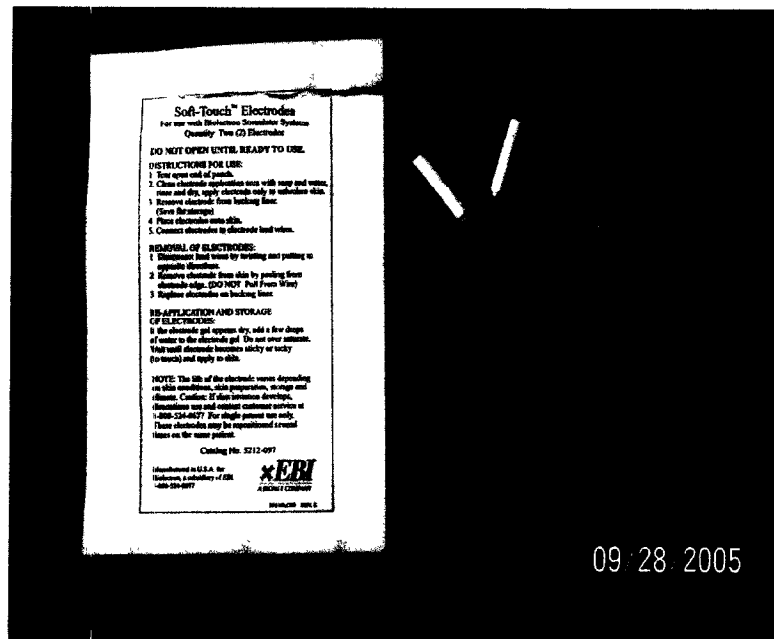


Figure 1. Soft-Touch™ Electrodes made by Uni-Patch



Figure 4. Current distribution map for Uni-Patch Soft-Touch Electrodes.

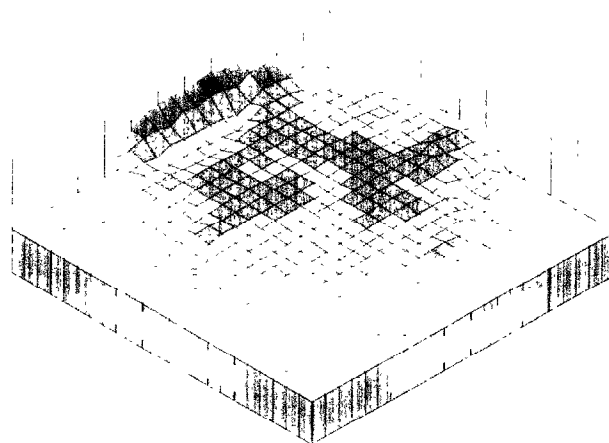


Figure 5. Current distribution map for Uni-Patch Soft-Touch Electrodes.